	Type	L #	Hits	Search Text	DBs	Time Stamp	Comments
1	BRS	L1	30	increment$ same balloon same expansion and stent and catheter	USPAT; US-PGPUB; DERWENT	2003/12/17 17:40	
2	BRS	L2	4	increment$ adj6 balloon same expansion and stent and catheter	USPAT; US-PGPUB; DERWENT	2003/12/17 17:41	
3	BRS	L3	1	increment$ adj6 balloon same expansion and stent and catheter and (sheath or cover)	USPAT; US-PGPUB; DERWENT	2003/12/17 17:42	
4	BRS	L4	2	increment$ adj9 balloon same expansion and stent and catheter and (sheath or cover)	USPAT; US-PGPUB; DERWENT	2003/12/17 17:43	

	Error Definition	Errors
1		0
2		0
3		0
4		0

	Type	L #	Hits	Search Text	DBs	Time Stamp	Comments
5	BRS	L5	75	catheter same sheath same (slow$ or increment$) and balloon and stent	USPAT; US-PGPUB; DERWENT	2003/12/17 17:53	
6	BRS	L6	6	5868755.URPN.	USPAT	2003/12/17 17:47	
7	BRS	L7	4	catheter same sheath same increment and balloon and stent	USPAT; US-PGPUB; DERWENT	2003/12/17 17:54	
8	BRS	L8	15	catheter same sheath same increment$ and balloon and stent	USPAT; US-PGPUB; DERWENT	2003/12/17 17:54	

sposed on the catheter in the contracted condition.

Brief Summary Text - BSTX (8):

Embodiments may include one or more of the following features. The **balloon** is only initially radially constrained. The constraint is an axially slidable **sheath** which surrounds and partially constrains the **balloon** from inflation. The **sheath** is designed to axially slide along a length of the **balloon** in response to a pressure in the **balloon, such that the balloon** may be progressively **incrementally** inflated. The slidable **sheath** is adapted to slide axially onto a shaft of the **catheter** so that the **sheath** may be retrieved from the patient. The constraint is an elastomeric band which surrounds and partially constrains the **balloon** from inflation. The elastomeric band is disposed over a significant length of the **balloon**. The elasticity of the elastomeric band varies, e.g., by varying the thickness of the bond, from one end of the **balloon** to the other to allow progressive **incremental** inflation of the **balloon**. The elastomeric band has uniform elasticity over the portion of the **balloon** on which it is disposed. The elastomeric band is disposed only over a center region of the **balloon** and divides the **balloon** into a proximal and a distal region. The tubular prosthesis is a **stent**. The **balloon** is substantially nondistendible. The constraint is an axially slidable **sheath** which surrounds the **balloon, the sheath** being formed of a low coefficient of friction polymer. The polymer is teflon. The **balloon** has an inflatable portion corresponding to the length of the prosthesis and the **balloon** and prosthesis have a length of about 5 cm or more. The **balloon** and prosthesis have a length in the range of about 8-12 cm. The

DOCUMENT-IDENTIFIER: US 20030144671 A1

TITLE: Delivery mechanism for implantable **stents**-grafts

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Abstract Paragraph - ABTX (1):
A delivery mechanism for an implantable **stent** which provides a high mechanical advantage to the surgeon and convenient operation so as to facilitate smooth withdrawal of an outer **catheter sheath** following placement of the **stent** in the desired location within the patient's vessel. Preferred embodiments include a moving rail actuated by a V-shaped lever, a hydraulic actuator, a rack and pinion drive, and a power screw system. The delivery mechanism has a movable member that is attached to the outer **catheter sheath** so that actuating the mechanism results in an **incremental** movement of the moveable member, which in turn results in an **incremental** movement of the outer **catheter sheath**. Once the outer **catheter sheath** is retracted from the **stent, the stent** is deployed into the patient's vessel and the remaining parts of the mechanism, including an inner tube, an atraumatic tip, and a stabilizing element, are easily removed.

Title - TTL (1):
Delivery mechanism for implantable **stents**-grafts

Summary of Invention Paragraph - BSTX (2):
[0002] The present invention relates to implantable medical devices. More particularly, the present invention relates to mechanisms

for implanting a
self-expanding **stent** graft which is used to sustain a weakened body vessel.

Summary of Invention Paragraph - BSTX (5):
[0004] A commonly used implant is a tubular-shaped wire frame known as a
stent graft. In one type of **stent** graft, the wire frame is made of
self-expanding nickel-titanium (nitinol) shape memory alloy which is laser cut
and encapsulated within two layers of expanded polytetrafluoroethylene (ePTFE).
The layers of ePTFE are processed such that the material forms a monolithic
structure, fully enclosing the metallic **stent** where the cover is present. The
encapsulation is intended to prevent restenosis of the vessel. The inner blood
contacting lumen of the **stent** graft is impregnated with carbon. Typically, one
or both ends of the **stent** graft is flared and free of encapsulation in order to
facilitate anchoring within the vessel. The nitinol alloy is placed into the
body during surgery at room temperature. As it increases to body temperature,
it expands to its desired size. **Balloon** angioplasty may be done after
implantation of the **stent** to set its final shape.

Summary of Invention Paragraph - BSTX (6):
[0005] In order to introduce the **stent** into the body vessel, it is placed
within a tubular sheath catheter. When the device is positioned at the desired
location, it is released from the tubular sheath and permitted to expand
radially against the wall of the vessel. When the outer sheath is removed, the
physician must be careful to avoid migration of the **stent** away from the desired
location. Typical prior art devices employ a simple ratchet mechanism in
conjunction with the outer sheath and an inner lumen. The

inner lumen is
maintained stationary to fix the **stent** in position and the outer lumen is drawn
away from the **stent** by means of the ratchet mechanism actuated by a spring
loaded trigger. Each pull on the trigger causes the outer sheath to retract by
an amount corresponding to the stroke of the trigger. An anchor to which the
outer sheath is attached includes a tooth which engages with each tooth of the
ratchet mechanism. This mechanism has drawbacks in that it is awkward to
operate and difficult to maintain steady so that the **stent** graft does not
migrate away from its desired position during sheath retraction.

Summary of Invention Paragraph - BSTX (8):

[0006] The present invention is directed to a **stent** delivery mechanism which
is both easy to operate and facilitates extremely precise **stent** positioning.
Several different configurations are described. For example, in a first
embodiment, a simple V-shaped grip aligned generally longitudinally with the
catheter to be deployed is utilized. A mechanical advantage gear mechanism is
employed, which operates in conjunction with a ratchet to smoothly retract a
sheath hub to which the outer sheath of the catheter is attached. The
mechanism is easy to grasp and actuate in any rotational configuration. The
V-shaped mechanism includes a body which contains the ratchet and a drive gear
lever handle. The lever handle interacts with a drive pinion to drive the
ratchet by a predetermined amount, thus retracting the sheath hub by a
corresponding amount. The drive gear lever handle mechanism provides both the
mechanical advantage, which results in movement of the outer sheath by a
relatively small amount for a large displacement of the lever handle, and a

much smoother operation than the direct ratchet operation of the prior art
device.

Summary of Invention Paragraph - BSTX (12):
[0010] In order to further facilitate the **stent** deployment, the inner lumen
of the delivery system may be formed of a metal spring, which is contained in
its fully compressed state. The use of such a spring for the inner lumen
provides significant advantages in that it is extremely flexible, enabling
introduction of the catheter into the body and proper positioning of the **stent,**
and yet is very rigid and non-compressible so as to maintain the **stent** in the
desired position during outer sheath retraction.

Brief Description of Drawings Paragraph - DRTX (2):
[0012] FIG. 1 is a cross-sectional view of the end of a catheter
illustrating a **stent** to be implanted;

Brief Description of Drawings Paragraph - DRTX (3):
[0013] FIG. 2 is a cross-sectional view of a first embodiment of the **stent**
delivery mechanism of the present invention incorporating a moving rail
mechanism;

Brief Description of Drawings Paragraph - DRTX (5):
[0015] FIG. 7 is an exploded view of a preferred embodiment of the **stent**
delivery mechanism shown in FIG. 2.

Brief Description of Drawings Paragraph - DRTX (6):
[0016] FIG. 8 is a cross-sectional view of a second embodiment of the **stent**
delivery mechanism of the present invention incorporating a hydraulic mechanism

Brief Description of Drawings Paragraph - DRTX (8):
[0018] FIG. 13 is a cross-sectional view of a third embodiment of the **stent** delivery mechanism of the present invention employing a rack and pinion thumb actuated drive system;

Brief Description of Drawings Paragraph - DRTX (11):
[0021] FIG. 17 is a cross-sectional view of a fourth embodiment of the **stent** delivery mechanism of the present invention employing a power screw drive system;

Detail Description Paragraph - DETX (4):
[0026] FIG. 1 illustrates the distal end of a catheter 11 having a **stent** 16 carried within it for implantation into the body of a patient. The proximal end of the catheter 11 is connected to any of the delivery mechanisms to be described, and the catheter 11 is of sufficient length to reach the point of implantation of the **stent** 16 from the introduction point into the body. The catheter 11 includes an outer sheath 10, a middle tube 12 which in the preferred embodiment is formed of a compressed spring, and a flexible (e.g., polyamide) inner tube 14. The outer sheath 10 preferably has an ePTFE liner with a polyether blocked amide plastic (pebax) basecoat with reinforced braid, and an external layer of pebax. A **stent** 16 for implantation into a patient is carried within the outer sheath 10. The **stent** 16 includes a nitinol memory metal alloy frame 18 which is formed in a criss-cross pattern which may be laser cut. Most or all of the length of the **stent** is encapsulated within two layers of ePTFE to form a monolithic body structure 20, fully enclosing the metallic **stent** 16 both internally and externally where the cover 20 is present.

One or both ends of the **stent** 16 may be left uncovered as illustrated at 22 and 24 to provide anchoring within the vessel where the **stent** 16 is to be implanted.

Detail Description Paragraph - DETX (6):

[0028] A generally cup-shaped element 28 is provided within the catheter 11 adjacent the rear end of the **stent** 16 and is attached to the end of the spring 12 by appropriate means, e.g., the cup element 28 may be plastic wherein the spring 12 is molded into its base, or the cup element 28 may be stainless steel wherein the spring 12 is secured by welding or the like. The open end of the cup element 28 serves to compress the end 24 of the **stent** 16 in order to provide a secure interface between the **stent** 16 and the spring 12. Alternatively, instead of a cup shape, the element 28 could be formed of a simple disk having either a flat or slightly concave surface for contacting the end 24 of the **stent** 16.

Detail Description Paragraph - DETX (7):

[0029] In order to deploy the **stent** 16 inside a body vessel during a surgical procedure, the catheter 11 is introduced into the designated vessel via an introducer positioned at the skin of the patient. As mentioned above, a guide wire may have previously been introduced into the vessel, in which case the catheter 11 is introduced by passing the tip 26 over the end of the guide wire outside of the patient and moving the catheter 11 along the path within the vessel which has been established by the guide wire.

Detail Description Paragraph - DETX (8):

[0030] The position of the catheter 11 is tracked by monitoring the tip 26

by means of a fluoroscope. When the catheter 11 is at the desired location
i.e., when the **stent** 16 is positioned at the location where it is be implanted,
the movement of the catheter 11 is halted. The catheter 11 must then be
removed, leaving the **stent** 16 in place at the desired location within the
vessel. This is accomplished by initially retracting the outer sheath 10,
i.e., towards the left in FIG. 1, until it no longer covers the **stent** 16. The
spring 12 is maintained in a fixed position and, in conjunction with the cup
element 28, serves to maintain the **stent** 16 in its desired position during the
retraction of the outer sheath 10. After the outer sheath 10 has been
retracted such that it no longer covers the **stent** 16 and the **stent** 16 is
expanded, the tip 26 can be pulled back through the **stent** 16 until the tip 26
abuts the outer sheath 10. As illustrated, the diameter of the tip 26 is
slightly greater than the inner diameter of **stent** 16 when it is inside the
outer sheath 10. The **stent** 16 will expand as it heats up to body temperature
as a result of its memory metal characteristics. The tip 26 is then pulled
through the center of the **stent** 16 after the **stent** 16 has expanded following
withdrawal of the sheath 10. Once the tip 26 has been pulled back against the
outer sheath 10, the catheter 11 can be removed from the vessel of the patient.
This retraction procedure ensures that the tip 26 does not get caught on or
embedded in any body vessel when being pulled out of the patient.

Detail Description Paragraph - DETX (9):

[0031] As discussed above, the tube spring 12 is maintained stationary
during the withdrawal of the outer sheath 10 and serves to keep the **stent** 16 in

its desired location. The tube spring 12 is very well suited for this task since it has extremely low compression in a longitudinal direction once it is fully compressed. It is also well suited for the introduction of the catheter 11 into the body vessel, since it is extremely flexible. Alternatively, other materials, such as various plastics materials, could be employed as the middle tube 12, so long as the compression is low to maintain **stent** positioning and the necessary flexibility is provided for moving through the vessel. In order to properly deploy the **stent** 16, the outer sheath 10 must be smoothly retracted while the tube spring 12 maintains its position. The present invention provides a number of mechanisms intended to perform this operation with maximum ease of use and minimal **stent** migration.

Detail Description Paragraph - DETX (10):

[0032] FIG. 2 illustrates a first embodiment of a delivery mechanism for implanting the **stent** 16. This mechanism is generally in the form of a V-shaped lever device having a housing shell 30 from which the outer sheath 10 extends. The sheath 10 is secured to a pawl/sheath hub 32. A spring pawl 34 attached to the hub 32 engages a ratchet 36 which is integrated into the housing shell 30. Movement of the sheath hub 32 within the housing shell 30 is thus constrained to moving to the right as shown in FIG. 2. The tube spring 12 is secured in a fixed position to a guide wire port 38. The interior of the device may be. flushed by means of a flush stop cock 40. A ratchet rail 42 is provided at the bottom of the housing shell 30 and is reciprocal back and forth within the shell 30. The rail 42 includes ratchet teeth 44 on the upper side which engage with the spring pawl 34 and a rack gear 46 on the bottom surface thereof which

engages a pinion 48. The pinion 48 is rotated by means of a lever handle 50 which includes a drive gear 52. The lever handle 50 is spring biased by means of a spring 54 to its open position. Other types of springs, such as a spring contained within the pivot point 56 of the lever handle could alternatively be employed.

Detail Description Paragraph - DETX (12):

[0034] The described device is intended for use with **stents** of approximately 40-100 mm in length. In order to fully retract the outer sheath 10, the lever handle 50 must be closed and opened a number of times. FIG. 6 illustrates the mechanism in which the handle 50 has been operated to move the hub 32, and therefore the outer sheath 10, back to its completely rightmost position. In this position (or sooner depending upon the length of the **stent**) the outer sheath 10 will be completely away from the **stent** 16, allowing the **stent** 16 to expand. As described above, once the **stent** 16 expands, the inner tube 14 and tip 26 are pulled back through the middle of the **stent** 16 until the tip 26 is tight against the outer sheath 10. The entire catheter 11 can then be removed, leaving the **stent** 16 in place at the desired location.

Detail Description Paragraph - DETX (13):

[0035] A preferred embodiment of the device shown in FIG. 2 is illustrated by the exploded view in FIG. 7. In this view, a left housing assembly 31 and a right housing assembly 33 can be seen. An inner catheter assembly 37 is disposed between the housing assemblies 31 and 33 to support the tube spring 12 as well as the spring pawl 34. A strain relief member 51 fits over the end of housing shell 30 to reduce any potential pressure caused in the actuation of

the mechanism. A safety pin 53 is insertable into the lever handle 50 for additional protection. Upon completion of the deployment of the **stent** 16 and the retraction of outer sheath 10, a retractor sleeve 49 is pulled back slightly, releasing a retractor latch 47 from its locked position on the inner catheter assembly 37. The inner catheter assembly 37, which is coupled to the inner tube 14, is pulled back away from the housing assemblies 31 and 33 in order to retract the inner tube 14 far enough so that tip 26 is snuggly against the outer sheath 10. The catheter 11, including the outer sheath 10, the inner tube 14 and the tip 26 can then be removed from the body. Retraction of the catheter 11 in this manner ensures that the tip 26 can not get caught on anything outside of the body or inside the delivery mechanism.

Detail Description Paragraph - DETX (14):

[0036] The gear mechanism including the lever gear 52, pinion 48 and rack 46 is designed to provide a mechanical advantage of approximately 4:1. The mechanical advantage along with the rotating pinion configuration provides very smooth and linear operation with minimal fly back during the return stroke. In addition, the lever handle configuration is extremely convenient, as it can be easily operated in almost any rotational orientation. This is important due to the fact that when a catheter is introduced into the patient, it is often necessary to rotate the catheter in order for it to most easily follow the desired path through the vessel to the **stent** location. Therefore, the final orientation when the **stent** is to be deployed is variable. The configuration of the V-shaped lever handle mechanism enables a simple gripping action to be applied, and is easily gripped by the surgeon regardless of

its final
orientation. Generally, approximately ten cycles (i.e., squeezing and
releasing) of the lever handle 50 are necessary to fully remove the outer
sheath 10 from the **stent**. The configuration of this embodiment enables
retraction to be done in a very smooth and linear fashion.

Detail Description Paragraph - DETX (15):

[0037] A second embodiment of the **stent** delivery mechanism is illustrated in
FIG. 8. This delivery mechanism employs a hydraulic system to achieve
extremely smooth operation. A housing 62 defines a reservoir chamber 64 within
which is carried a piston 66. The outer sheath 10 is connected to the piston
66 to be moved therewith. A V-cup seal 68 prevents leakage of the hydraulic
fluid carried within the housing. A piston displacement chamber 70 is defined
between the piston 66 and the opening through which the sheath 10 exits.

Detail Description Paragraph - DETX (18):

[0040] Referring to FIG. 11, the plunger 80 is pressed inward to open the
valve 78 and move fluid through the conduit 74 into the piston chamber 70, thus
moving the piston 66 to the right by a fixed amount and, in turn, retracting
the outer sheath 10 from the **stent**. In the present embodiment, one stroke of
the plunger 80 provides approximately 1 cm of travel of the piston 66. The
plunger and piston are sized to provide a mechanical advantage of approximately
4:1. By repeatedly operating the plunger, the piston 66 will be drawn back to
its fully deployed position as illustrated in FIG. 12. At this point, the
outer sheath 10 is fully withdrawn from the **stent** 16, and the catheter 11 can
be pulled out of the patient as described above.

Detail Description Paragraph - DETX (21):

[0043] In operation, the knob 90 is rotated counterclockwise as illustrated in FIG. 15, causing the gear 92 to move in the same direction. This action causes the reduction drive gear 88 and the rack drive gear 86 to move in a clockwise position, which in turn causes the rack 84 to retract within the housing by a distance of approximately 1 cm per revolution of the knob as indicated at 94. The mechanical advantage is controlled by appropriate sizing of the gears which drive the rack 84. After a sufficient number of rotations, the rack 84 will be fully retracted, as illustrated in FIG. 16 and the outer sheath 10 will be completely removed from the **stent** 16 so that the catheter 11 can be removed from the patient as described above.

Detail Description Paragraph - DETX (23):

[0045] As shown in FIG. 19, a single rotation of the knob 96 achieves a movement of the power screw 104 of approximately 1 cm, as indicated at 106. The high mechanical advantage provided by the configuration facilitates smooth retraction of the outer sheath 10. After a number of rotations of the knob 96, the power screw 104 will be fully retracted, as illustrated in FIG. 20, and the outer sheath 10 will be completely withdrawn from the **stent** 16. The catheter 11 can then be removed as described above.

Detail Description Paragraph - DETX (24):

[0046] In summary, each of the disclosed systems provides a significant mechanical advantage which facilitates smooth retraction of the outer sheath 10 which covers the **stent** 16. This minimizes migration of the **stent** 10 during sheath retraction, thus ensuring that the **stent** 16 will remain in its desired

location. In addition, various configurations are provided which are operable
in numerous orientations, thus providing convenient and simple use during
surgery.

Claims Text - CLTX (2):

1. A **stent** deployment system for introducing a self-expanding **stent** into a
body vessel, comprising: an inner catheter having a proximal end and a distal
end, the distal end being attached to a tip, the inner catheter permitting
passage of a guidewire therethrough; a reinforcing spring element surrounding
the inner catheter for resisting compression and providing flexibility for
moving through a body vessel; an abutment element attached to a distal end of
the reinforcing spring element for preventing axial movement of the
self-expanding **stent** in a proximal direction; and an outer catheter having a
proximal end and a distal end, the proximal end being attached to a movable
member, the distal end surrounding the self-expanding **stent**, wherein movement
of the movable member retracts the outer catheter to release the self-expanding
stent.